K990221

Premarket Notification (510(k)) Summary

JUN 2

Product Name: IntraCoil™ Peripheral Stent

Common Name: Tracheal prosthesis

Class: III per 21 CFR §878.3720 (tracheal prosthesis)

Submitter's Name:
IntraTherapeutics, Inc.
6271 Bury Drive
Eden Prairie, MN 55346

Official Contact:
Amy Peterson
Vice President RA and QA
Telephone: 612-937-0322
Fax: 612-937-0312

Summary Preparation Date: January 21, 1999

This summary is provide in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission. Substantial equivalence is claimed to Boston Scientific, Inc. legally marketed Ultraflex™ and Wallstent® self-expanding tracheobronchial stents (K963241 & K982184, respectively).

IntraTherapeutics, Inc. (ITI) IntraCoil stent is a self-expanding nickel-titanium (Nitinol) coil premounted on a delivery catheter. The intended use is "in the treatment of bronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted". Upon deployment the ITI stent expands to conform to the bronchial lumen surface. The stents' purpose is to increase or maintain the inner lumenal diameter of the bronchial passage.

Summary of technological characteristics: the ITI stent and predicate stents are all self-expanding stents fabricated from wire (Nitinol or elgiloy) into a tubular configuration, packaged and sterilized. The ITI and predicate stents are ethylene oxide (ETO) sterilized. *In vitro* tests to assess performance characteristics were performed as outlined in FDA document "Guidance for the content of premarket notifications for esophageal and tracheal prostheses", dated April 28, 1998 and biocompatibility standard ISO 10993 using finished product.

As demonstrated the ITI stent is identical in materials, and equivalent for indication for use and technological characteristics. The collective evidence therefore provides assurance that the ITI IntraCoil peripheral stent meets the requirements for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Amy Peterson
Vice President, Regulatory Affairs and
Quality Assurance
Intratherapeutics,Inc.
6271 Bury Drive
Eden Prairie, MN 55436

MAY 25 1999

Re: K990221
IntraCoil ™ Peripheral Stent
Dated: March 25, 1999
Received: March 29, 1999
Class: III

Dear Ms. Peterson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed the scientific review portion of your premarket notification (510(k)) referenced above. Final clearance of a 510(k) for a class III device requires an FDA inspection that finds the manufacturing facilities, methods and controls in compliance with the applicable device Good Manufacturing Practice (GMP) Regulations (21 CFR Part 820). CDRH will issue a substantially equivalent letter after the inspectional findings have been reviewed and determined to be acceptable. You may not begin commercial distribution of the device manufactured at your facility(ies) until you have received a substantially equivalent letter.

If you have a manufacturing facility which is not prepared for production of the device, amend the 510(k) as soon as possible and notify your District Office to indicate when the facility will be prepared to produce the device so that the FDA inspection can be rescheduled. Where appropriate, amend the 510(k) to include any relevant information regarding the manufacturing facilities, methods or controls not previously submitted. If you have any questions regarding the status of your GMP inspection please contact your District Office or the Office of Compliance, CDRH at (301) 594-4695. All information regarding this 510(k) should be submitted in duplicate to the address below and reference the above 510(k) number to facilitate processing.

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning this letter, please contact the Premarket Notification 510(k) Section at (301) 594-1190.

Sincerely yours,

Heather S. Rosecrans

Heather S. Rosecrans
Chief, Premarket
Notification Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 1999

Ms. Amy Peterson
Vice President, Regulatory Affairs and
Quality Assurance
Intratherapeutics, Inc.
6271 Bury Drive
Eden Prairie, Minnesota 55436

Re: K990221
Trade Name: IntraCoil™ Peripheral Stent
Regulatory Class: III
Product Code: JCT
Dated: March 25, 1999
Received: March 29, 1999

Dear Ms. Peterson:

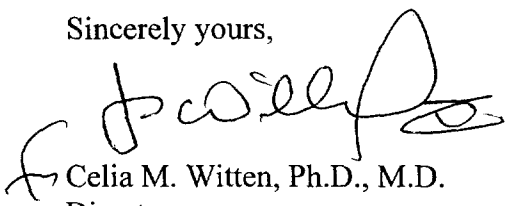
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if know): K990221

Device Name: ITI IntraCoil™ Peripheral Stent

Indication For Use:

The ITI IntraCoil™ Stent is indicated for use in the treatment of bronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTIUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990221

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)